

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 98F-0675]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

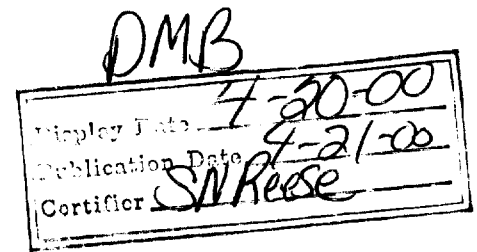
SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polyethylenepolyamines as cross-linking agents for epoxy resins in coatings intended for use in contact with food. This action responds to a petition filed by the Dow Chemical Co.

DATES: This rule is effective [*insert date of publication in the Federal Register*]; submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 24, 1998 (63 FR 45073), FDA announced that a food additive petition (FAP 8B4606) had been filed by The Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300)



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to provide for the safe use of polyethylenepolyamines (PEPA's) as cross-linking agents for epoxy resins in coatings intended for use in contact with food.

In its evaluation of the safety of PEPA's, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although PEPA's have not been shown to cause cancer, they could contain minute amounts of unreacted starting material, ethylene dichloride (1,2-dichloroethane), a carcinogenic impurity. However, FDA concludes that 1, 2-dichloroethane is not likely to be present in the final food contact material in an amount that could present a safety concern for the following reasons. Based on the low boiling point of 1,2-dichloroethane relative to PEPA's, residual 1,2-dichloroethane would be expected to be removed during any purification process of PEPA's. Any residual 1,2-dichloroethane in PEPA's would also be expected to be removed on curing of epoxy resins with PEPA's. In addition, because epoxy resins cured with PEPA's will be allowed only for repeat-use applications, any 1,2-dichloroethane that could be present in food would be minimized by evaporation and washing of the surface before food is added and by the large volume of food in contact with the cured resin over its service lifetime. Based on this information, the agency concludes that the proposed use of the additive is safe, and that the additive will achieve its intended technical effect. Therefore, the agency concludes that the regulations in § 175.300 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4606 (63 FR 45073). No new information or comments have

been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before *[insert date 30 days after date of publication in the **Federal Register**]*, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 175.300 is amended in paragraph (b)(3)(viii)(*b*) by alphabetically adding an entry to read as follows:

§ 175.300 Resinous and polymeric coatings.

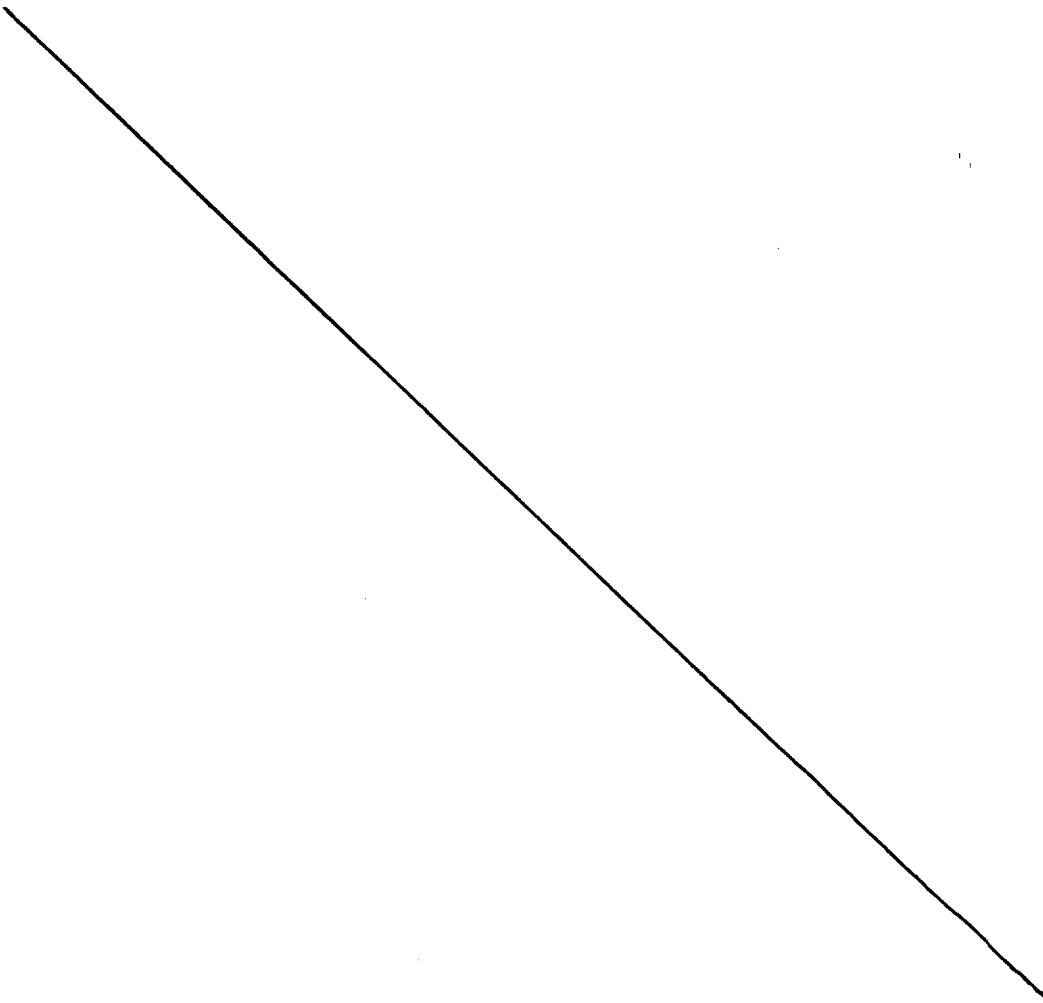
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(b) * * *

(3) * * *

(viii) * * *

(*b*) * * *



Polyethylenepolyamine (CAS Reg. No. 68131-73-7), for use only in coatings intended for repeated use in contact with food, at temperatures not to exceed 180 °F (82 °C).

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Dated: 4/14/00
April 14, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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